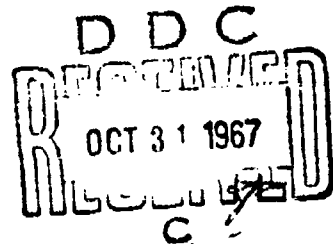


AD660290

QUARTERLY PROGRESS REPORT

Period Covered
July-August-September
1967



U.S. ARMY MEDICAL BIOMECHANICAL RESEARCH LABORATORY
WALTER REED ARMY MEDICAL CENTER
Washington, D. C. 20012

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In conducting the research described in this report, the investigators adhered to the "Guide for Laboratory Animal Facilities and Care", as promulgated by the Committee on the Guide for Laboratory Animal Resources, National Academy of Sciences - National Research Council.

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I. RESEARCH AND DEVELOPMENT ITEMS

ADHESIVES; TISSUE

Several batches of methyl, n-butyl, hexyl and heptyl alpha cyanoacrylates were prepared to replenish the supply of monomers for experimental work. The ^{14}C tagged n-butyl cyanoacrylate was also prepared for in vivo degradation studies.

In vitro studies on the aqueous degradation of polymers of cellosolve and cyclo-hexyl cyanoacrylates showed that their degradation rates under heterogeneous conditions were higher than poly-2-ethyl-hexyl cyanoacrylate but lower than other polymers from branched chain alcohol esters like isopropyl, isobutyl and isoamyl. A technical report on in vitro aqueous degradation of poly alpha cyanoacrylates is being written.

Studies of the rates of degradation in vivo of poly methyl, n-butyl, isoamyl, and a mixture of 95 parts of n-heptyl and 5 parts of methyl alpha cyanoacrylate indicated that methyl degrades fastest and is followed sequentially by isoamyl, 95 parts n-heptyl, 5 parts methyl, isobutyl, and n-butyl. A technical report is being written summarizing these results.

Additional work was done on the isolation and identification of metabolic products from the urine of dogs having ^{14}C cyanoacrylate implants (^{14}C in beta position). After removal of urea and insoluble barium salts of acids and water, a residue (25 g) was obtained which contained 95% of the total ^{14}C activity of the seven liters of urine (6×10^6 dpm). The residue is neutral, soluble in water and methyl alcohol, but insoluble in acetone and isopropyl alcohol. It formed a complex with HCl from which HCl could not be removed by washing with acetone or azeotropic distillation with water. Autoradiography combined with a thin layer chromatography is being applied for the further study of the isolated radioactive extract.

In the polymerization studies of n-heptyl alpha cyanoacrylate it was found that, when polymerization was carried out in aqueous solution of glycine (^{14}C tagged), glycine was incorporated in the poly n-heptyl alpha cyanoacrylate to a similar extent to that of polymethyl alpha cyanoacrylate prepared under the same conditions.

The clinical evaluation of the treatment of split thickness skin graft donor sites using alpha cyanoacrylate homologues is nearly complete. One more biopsy will be obtained in October and hopefully this, along with the pathology reports, will conclude this project. This material will then be prepared for presentation and publication. On 2 September 1967, in Vienna, Austria, at a Symposium on Tissue Adhesives in Surgery, a paper describing the results obtained was presented.

The tissue from the evaluation of four types of treatment (including n-butyl and n-heptyl alpha cyanoacrylate) of split thickness skin graft donor sites on minipigs and the tissue from the evaluation of cyanoacrylate for the control of post tonsillectomy hemorrhage and epistaxis has been transferred to the AFIP and is now being evaluated.

The study concerned with the cutaneous absorption of n-alkyl alpha cyanoacrylate ^{14}C is now complete. It was found by placing the methyl monomer on the backs of two catheterized rats that cutaneous absorption definitely occurs. A paper has been written and will soon be submitted for publication.

The study to evaluate digestive tract (oral and gastrointestinal) absorption of methyl and n-butyl alpha cyanoacrylate ^{14}C has been started. No results are available at this time.

The project to evaluate the LD₅₀ of orally ingested n-butyl alpha cyanoacrylate polymer powder is continuing. To date, none of the animals has died. The dose range goes up to a level equivalent to a 150 pound man eating 20 pounds of cyanoacrylate in ten days. All of the animals have continued to gain weight similar to controls. This project will be complete, except for pathology, in approximately ten weeks.

After a period of 21 months, dogs, whose surgically traumatized livers had been treated with isobutyl, heptyl and n-butyl alpha cyanoacrylate, were sacrificed. Tissue studies are being made.

Six dogs, with various monomers implanted in liver wounds, are being held at Forest Glen until death, to evaluate the fate of the polymer and its effect on the host.

During this period, 10 dogs have been sacrificed in which perforated intestinal wounds have been sealed with "Aerosol" spray using n-butyl alpha cyanoacrylate. The term of study varies from one month to six months. The histological evaluation of the tissue is in progress.

ARTERIAL GRAFTS

Experiments are being carried out toward the preparation of non-thrombogenic polymer films. During this period, vinyl pyridine, dimethyl-aminoethyl methacrylate and quaternized dimethylaminoethyl methacrylate and hydroxyethyl methacrylate have been copolymerized with ethyl and

butyl acrylates yielding elastomeric terpolymers.

Capillary tubes are being made coated with these polymers for zeta potential studies. Coated tubes were also prepared from L + lactic acid polymer and from poly benzyl L-glutamate and from copolymers of benzyl glutamate/L-Alanine and γ benzyl glutamate/L-Leucine.

Zeta potentials were determined according to the method described in J. Applied Physiology 18, 1263-1265 (1963). Measurements in this laboratory gave a value of -22.1 mv as compared with the values reported in reference cited of -28.0 mv for glass capillaries. Poly γ benzyl glutamate coated glass capillary gave a value of -29.3 mv.

During this period, standard 10 acrylate-amide tubes with helical reinforcement were made and flared test prostheses for vena cava implantations were fabricated. Attempts were made to aminate several hydroxyl bearing copolymers with ethylene imine. To date the results are not definitive.

BIODEGRADABLE POLYMERS

Several experiments were run to determine the effect of purity of the monomeric lactides on the final molecular weights of the polymers obtained. Results show that the higher the purity of the dl or L (+) lactide crystallized out from acetone and methyl alcohol, the higher the molecular weight of the final polymer and the more suitable it was for drawing fibers from the melts and casting films. The samples of the dl and L (+) polylactic acid polymers having an inherent viscosity of 1.6 in 80:20 mixture of phenol:trichlorophenol have been prepared for experimental purposes.

Several batches of polypeptides were prepared from γ benzyl L-Gly NCA, L-Ala-NCA and Cbz L-Lys-NCA for evaluating permeability.

BRACING; LOWER EXTREMITY

Two bilateral brace wearers have been fitted with drop-foot plastics braces. One patient has been wearing his braces 2 months with very satisfactory results. The other patient has been wearing his braces 2 weeks without incident.

Both of these patients were supplied with 3 sets of shoe adaptors which gave 0°, 5°, or 10° lift to the shoe.

A technical report has been published describing the fabrication technique and is ready for distribution.

A method is being developed to make the double rod brace fabrication technique much simpler. The new method consists of prefabricating the calf band in a series of standard sizes and riveting the rods to the band. A new shoe attachment has been designed to allow the angle of lift of the shoe to be changed without removing the shoe adaptor. A posterior unibar brace has been designed and two such braces have been fitted to patients.

The results of an extensive amount of stress and strain observations are currently being evaluated and organized for a report.

COLLAGEN TUBE DEVELOPMENT

Collagen tubes have been prepared by implanting polymer rods of varying molecular structures in rats. The tubes have been tested and the results are being analyzed.

EXERCISE UNIT, CONSTANT TORQUE

Technical Report 6708 for this item has been published and distributed and a manuscript has been prepared for publication. The photographs from Occupational Therapy and Physical Therapy have been made and those from the Orthopedic Service will be taken after the Zimmer fracture bed has been received and put in use. Drawings for a new case design for the unit were completed and sent to several manufacturers for price estimates. When this information is received, a cost and use comparison will be completed as requested by R&D Command.

EXTERNALLY POWERED PROSTHESES

ELBOW, ELECTRIC

Two of these units continue to be tested at New York University. A technical report has been written on the previous model which utilized a worm gear with a flexible drive shaft. The present model which incorporates a bevel gear drive system was also mentioned in the report. A third model which appears to overcome all of the shortcomings of the first two models has been designed and built. This device is currently undergoing a laboratory evaluation. At 10,500 cycles of operation, a spring broke in the free swing unlocking mechanism. This resulted in jamming of the elbow. Replacement of the spring returned the mechanism to operational form. Testing is continuing.

HAND, ELECTRIC

During this period, a paper was presented at the International Conference on Medical and Biological Engineering, Stockholm, Sweden on the development of this device. The research efforts of this laboratory pertaining to externally powered devices and the control of their functions was discussed with groups in Germany, Sweden, England, Yugoslavia and Israel. A trip report covering the details of these discussions is being prepared.

The hand was also demonstrated at the American Hospital Association Convention in Chicago, Illinois.

More efficient drive mechanisms are being investigated for possible incorporation in the next six models that will be fabricated. The printed circuits for these hands have been assembled and tested.

A new slippage sensor for the Army hand is presently under investigation. A copper foil, .002 in. thick, will be formed to the shape of the palmar side of the existing two position thumb. The foil will be nickel electroplated to a thickness of .005 in. at which time two steel rods approximately 0.08 in. diameter will be soldered at predetermined positions. This sensor assembly will again be electroplated to a final thickness ranging between .010 and .015 in. The final thickness of the foil is yet to be determined. Experimentation is currently under way to determine optimum foil thickness to maintain good rigidity and obtain high resonant frequency of vibration.

The two stainless steel rods will be coupled to two piezoelectric crystals oriented at right angles of each other. Such orientation will enable the hand to detect slippage from any given angle. It is expected that the new system will eliminate the null point problem in the existing system.

HAND, ELECTRIC, SIZE III

This hand is being redesigned to reduce weight. Wax models of the internal drive system are being fabricated to ensure fit before working prototypes are made.

HAND, SIZE V (V.O.)

Designs for the hand operating mechanism are under consideration. A backing plate has been designed and is being machined.

HAND, RESILIENT, SIZE V

The mechanical operating mechanisms, the foam fillers and cosmetic gloves for the prototype models of the right and left hands have been completed and assembled, laboratory accepted, and are ready for amputee evaluation.

HAND, RESILIENT, SIZE IV

The mechanical operating mechanisms have been fabricated and assembled, ready for making the foam filler and cosmetic glove.

HAND, RESILIENT, SIZE III

The operating mechanism for this hand size is being fabricated. This mechanism has been reduced in size to provide the necessary thickness to the foam filler and also a more pleasing cosmetic appearance of the hand.

HOOK, FLAC

Evaluation of two of these devices continues at New York University.

HOOK, VOLUNTARY OPENING, CENTER CONTROL

The design of a prototype system is in the final stages and will be completed within the next reporting period. This design will make the hook system truly versatile since, by reversing the rotation of the actuator pulley and the return torque spring, the hook will be converted to a voluntary closing hook. Also, external power can be used with this design with no major modifications to the system. In essence, the design comprises a three-in-one system. If found satisfactory for amputee usage, a conversion kit can be provided. However, initially, it will be constructed and tested as a voluntary opening-center control system. Overall cable excursion to operate the device is 2 inches and cable tension force of 10 pounds is necessary for a 5 pound prehensive force.

OPTICAL INSERTS - PROTECTIVE MASKS

During this reporting period, the inserts that were produced in accordance with the R&D contract were clinically evaluated. This evaluation indicated that all previous shortcomings had been resolved and the insert was acceptable.

This laboratory has recommended that type classification action be initiated on this item with the following changes in specifications:

The insert shall be one size 66 mm pupillary distance.

The strut angles shall have one outward angular bend 45°.

These changes will be incorporated in order to have one design of insert that will fit tank crew men, air crew men and users of the new M17A1 military protective masks.

The 66 mm PD was established from a recent survey of wearers of optical inserts, the average PD was 66.1 mm. The lens design will permit the full range of optical decentration. The standardization of one strut angle will enter only one item into the supply system.

SPLINT, BURN, SOFT FOAM

Clinical evaluation continues on this item.

MISCELLANEOUS

Ethylene-oxide sterilization on Cardiac and Foley catheters and its effect on tissues with gradual aeration:

In this study, 60 rats were used on implantation study, as per the Protocol, in an attempt to evaluate the aeration time to avoid local toxic effect of ethylene oxide.

A detailed histological study was done with special stains. The data in this study indicates that, after standard procedure of sterilization with ethylene oxide, the absorption rate by Foley (rubber) catheter is greater than the Cardiac (plastic) catheter, in a given time. A minimum of 72 hours' aeration, after initial sterilization with ethylene oxide, seems to be indicated prior to use clinically. A paper has been submitted for publication.

Ten canine parotid and ten canine submaxillary appliances for collecting saliva were completed and delivered to USAIDR, Major Uotinen, DC.

A paper on the tongue depressor developed for dog tonsillectomy has been written and will soon be submitted for publication.

SCALPEL, HEMOSTATIC

One prototype model which combines provisions for cutting as well as delivery of cyanoacrylate monomer for achieving hemostasis has been submitted to the Division of Experimental Surgery, WRAIR. One other model is being designed which will make use of the pre-packaged Freon propellant containers.

SPRAY GUNS, TISSUE ADHESIVE

A partial delivery of the commercially molded spray nozzles has been made. These nozzles are disposable, have been evaluated and are very satisfactory.

PRONATION-SUPINATION SANDBLOCK

Both a left and right hand unit are presently being evaluated; one with Teflon bushings and one with nylon bushings. The sharp edge of the guide channel has been shearing bits of the bushing material off and this is being corrected. However, the unit continues to bind when used by patients. Steel ball bushings have been ordered and will be incorporated into the sandblock in an attempt to obviate this problem.

BURN BED

Further progress is dependent on receipt of materials.

REHABILITATION LOOM

Weaving is one of the most frequently used activities in occupational therapy for a therapeutic exercise program. Usually a standard floor loom is modified in some manner to provide the particular exercise pattern which is needed for a particular patient. This approach requires numerous adaptations which are often makeshift and cumbersome. A project is being initiated to develop an exercise loom whose primary purpose will be to permit exercise of both upper and lower extremities. A half scale model is being fabricated for evaluation of the various approaches which can be used to provide patterns of motion for both upper and lower extremities, methods of providing resistance and/or assistance, and a simple method of adjusting the working height of the loom.

SHOULDER UNIT - PASSIVE ACTION - POSITIVE HYDRAULIC LOCK

Feasibility studies of a new type of shoulder unit are under way. It is foreseen that the system will be gravity actuated and locked into position by a system of hydraulic actuators. The shoulder unit will undergo rotations of + 20 degrees around its vertical axis. Arm and forearm will rotate around a horizontal axis to provide for functions such as toileting and feeding. Positive lock of the system will be accomplished manually or electrically depending on the type of system being used for elbow and terminal device.

BLADDER STIMULATOR

A new unit is being designed which will provide two independent outputs. The amplitude, frequency and period of each output can be individually controlled.

AUDIO-EMG

Optimization of the circuitry has been completed. A printed circuit version is being readied for patient evaluation.

IDENTIFICATION TAG COVERS

Fifty identification covers were prepared for use as standards for commercial procurement of this item.

DISPLAY TEACHING AID

A display demonstrating the processing technique for maxillofacial prostheses was prepared.

SWITCH, MUSCLE BULGE

A 3-position switch for electric prosthesis control has been designed, a prototype has been partially constructed and the drawings are currently being revised. The switch is being designed to be as flat as possible and has its longest dimension perpendicular to the line of activation.

II. PRESCRIPTION CLINIC ACTIVITIES

During this period, the following prostheses were prepared:

Cosmetic

- 1 - Eye socket, eye and lids
- 1 - Ear Prosthesis
- 1 - Eye and cheek prosthesis

- 1 - Partial hand, glove and filler
- 1 - Partial finger
- 1 - Shoulder cover and foam support
- 1 - Partial foot, cover and filler

Orthopedic

- 1 - Below-elbow arm
- 1 - Below-elbow electric arm
- 2 - Shoulder disarticulation
- 1 - Below-elbow
- 1 - Below-elbow condyle

III. PUBLICATIONS

Memorandum Reports

- MR 9 Spray Nozzle for Dispensing Tissue Adhesives
- MR 10 Heterogeneous Hydrolytic Degradation of 95/5 Radioactive Heptyl/Methyl Alpha Cyanoacrylate Copolymer
- MR 11 Force-Length Characteristics of Forearm Cineplasty
- MR 12 Nozzle for Dispensing Tissue Adhesive - First Model
- MR 13 Tissue Adhesive Dispenser - Dental Type
- MR 14 Lactide Polymerization Techniques and Polymeric Molecular Weights
- MR 15 Techniques in Lactide Preparation
- MR 16 Techniques for Glycolide Distillation
- MR 17 Methods of Copolymerizing Lactides and Glycolide
- MR 18 Newtonian Viscosities of n-butylcyanoacrylates
- MR 19 Polymer Preparation of n-carboxy Amino Acid Anhydrides

Technical Reports

- TR 6705 Outer Fiber Stresses in Long Leg Brace under Static Load
- TR 6706 Electronic Adjustable Prehension Hand

TR 6708 USAMBRL Exercise-Traction Unit

TR 6709 Plastics Drop-Foot Braces

TR 6710 Design of an Electrically Powered Prosthetic Elbow

Articles in Journals

N-ALKYL ALPHA CYANOACRYLATE MONOMERS AS A TISSUE ADHESIVE IN SURGERY OF INTERNAL ORGANS, by T. Matsumoto, K. C. Pani, R. M. Hardaway, III, F. Leonard. Milit Med 132:515-21, Jul 1967.

IV. STAFF ACTIVITIES

Dr. Fred Leonard attended a meeting of the American Society for Testing and Materials, Committee F-4 on Surgical Implants held at Johnson & Johnson Research Foundation, New Brunswick, New Jersey, 5-7 July.

CPT Stuart Houston, VC, visited Anahuac, Texas, conferring with personnel on the tissue adhesive project, 8 July, and attended the National Convention of the American Veterinary Association, Dallas, Texas, 9-13 July.

Mr. Lloyd L. Salisbury, Jr. and Mr. Leonard F. Marcus visited New York University relative to the clinical evaluation of the electric elbow, 10-11 July.

COL Peter M. Margetis, DC, made a project site visit to Northwestern University, Chicago, Illinois for the National Institute of Dental Research, National Institutes of Health, 10-14 July.

Dr. Ramchandra K. Kulkarni, Ph. D., attended the Engineering Summer Conference at the University of Michigan, Ann Arbor, Michigan, 10-21 July.

Dr. Fred Leonard attended the Gordon Research Conferences on Chemistry at Interfaces, Meriden, New Hampshire, 27 July, and presented a paper on "Interfacial Polymerization of Alpha Cyanoacrylates."

COL Peter M. Margetis, DC, lectured at the West Virginia State Dental Society meeting at White Sulphur Springs, West Virginia 31 July.

MAJ Mary H. Yeakel, AMSC, visited the Occupational Therapy Section, Fitzsimons General Hospital, Denver, Colorado, as a consultant on materials for orthotic appliances, 11-14 August.

Mr. Roy I. Katsuren completed a Managerial Statistics course at the American University, Washington, D.C., 11 August.

Mr. Lloyd L. Salisbury, Jr. and Mr. Albert B. Colman presented a paper on "An Electromechanical Hand with Automatic Proportional Control of Prehension," at the 7th International Conference on Medical and Biological Engineering, Stockholm, Sweden, 13-19 August. While abroad, Messrs Colman and Salisbury visited clinics in Germany, England, Sweden and Italy reviewing the status of the development of externally powered hands and arms.

COL Peter M. Margetis, DC, was guest lecturer for the Dental Officers, Valley Forge General Hospital, Phoenixville, Pennsylvania, 18 August, and lectured on restorative materials in dentistry.

Mr. Leonard F. Marcus made a return visit to New York University on 14-15 August relative to the clinical evaluation of the electric elbow.

MAJ Mary H. Yeakel, AMSC, was guest lecturer on splinting materials at the OT-PT Technician Class, U. S. Naval Hospital, Bethesda, Maryland, 15 August.

Dr. Clarence W. R. Wade attended the Biomedical Applications of Thin-Layer Chromatography Meeting, Philadelphia, Pennsylvania, 18-19 August.

Mr. Joshua Nelson and SP/4 Arturo L. Cervera served as narrators for the laboratory's exhibit and demonstrated the electromechanical hand for the Army Medical Service portion of the combined Federal Hospital Exhibit during the American Hospital Association meeting in Chicago, 21-24 August.

Dr. K. C. Pani, MD, attended the Symposium on Adhesives in Surgery, Vienna, Austria, 1-2 September, and presented a paper entitled, "Histotoxic Effects of Cyanoacrylates."

CPT Douglas K. Ousterhout, MC, presented a paper on "Clinical Treatment of Split Thickness Skin Graft Donor-Sites using Alpha Cyanoacrylate Homologues" at the Symposium on Adhesives in Surgery in Vienna, Austria, 1-2 September.

Dr. Fred Leonard presented a paper, "Biological Adhesives," at the Symposium on Adhesives in Surgery, in Vienna, Austria, 1-2 September.

Dr. Fred Leonard spent two weeks in Yugoslavia, 5-14 September, working on a VRA project on the development of externally powered hand and arm.

Mr. George Brandes attended the American Chemical Society meeting in Chicago, 10-15 September.

COL Peter M. Margetis, DC, served as Course Director, Science of Materials in Dentistry Course, given at WRAIR, Walter Reed Army Medical Center, Washington, D.C., 11-15 September.

Dr. Fred Leonard spent two weeks in Israel on a VRA project on the application of plastics to braces, 14-28 September.

CPT Stuart Houston, VC, attended the Pathology of Laboratory Animals Course at AFIP, Washington, D.C., 18-22 September.

Mr. Harold J. Porter enrolled in an Advanced Physical Chemistry course at the Graduate School, U. S. Department of Agriculture, Washington, D.C., 18 September.

Mr. James C. Eaton, Jr., enrolled in an Introductory Biochemistry course at the National Institutes of Health, Bethesda, Md., 18 September.

Mr. Roy I. Katsuren enrolled in a Computer Programming course at the American University, Washington, D.C., 20 September.

Mr. Roger P. Hancock enrolled in a General Biology I course at the American University, 20 September.

COL Peter M. Margetis, DC, presented a paper on "Polymers in Dental Surgery," at the Plastics in the Medical Sciences Conference in New York, 21-22 September.

COL Peter M. Margetis, DC, visited Prodesco, Inc., relative to weaving of arterial grafts in Perkasio, Pennsylvania, 26 September.

V. PERSONNEL CHANGES

Gains

LTC Albert J. Luban, MSC, Executive Officer, reported for duty 1 September.

Mrs. Dorothy M. Wilbur, DAC, Secretary-Steno, reported for duty 5 September.

Mr. Roger P. Hancock, DAC, Mechanical Engineer (Applied Mechanics) reported for duty 3 July.

PFC Ronnie Ortner reported on special duty as Mechanical Engineer,
17 July.

PVT Catherine L. Barton, Clerk-Typist, reported for duty 14 September.

SSG Stephen J. Gruber, Medical Supply Sergeant, reported for duty
17 July.

Losses

1LT Aloys Wartner, MSC, Administrative Officer, departed 31 July.

Mrs. Vickie L. Wartner, DAC, Secretary-Steno, departed 14 July.

Mrs. Diane A. McCormick, DAC, Library Aide, departed 11 August.

SP4 Henry G. Mouhot, Chemical Engineer Assistant, departed
21 September.

SP5 Walter F. Pribil, Administrative Specialist, departed 15 September.